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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,757	06/23/2005	Amjad Ali	21158P	9113

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1628	

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10/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,757	ALI ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4 and 6-11* is/are allowed.

6)☒ Claim(s) *12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Claims 1-4 and 6-11 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 12-16, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on February 6, 2009 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

3. The rejection of claim 5 under 35 USC 112, first paragraph, scope of enablement is made moot by the cancellation of the instant claim.

4. The rejection of claims 1-4 and 6-11 under 35 USC 112, first paragraph, scope of enablement is withdrawn.

5. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for slowing the progression of a disease, does not reasonably provide enablement for preventing the onset of a disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to (a) a method of treating a variety of conditions by administering an amount of the claimed compound effective for treating said conditions or (b) modulating, i.e., activating, repressing, agonizing and/or antagonizing, the effects of glucocorticoid receptor.

The present specification defines "**treating**" and "**amount effective for treating**" as:

> The term "treating" encompasses not only treating a patient to relieve the patient of the signs and symptoms of the disease or condition but also prophylactically treating an asymptomatic patient to prevent the onset of the disease or condition or preventing, slowing or reversing the progression of the disease or condition. The term "amount effective for treating" is intended to mean that amount of a drug or pharmaceutical agent that will elicit the biological or medical response of a tissue, a system, animal or human that is being sought by a researcher, veterinarian, medical doctor or other clinician. The term also encompasses the amount of a
>
> pharmaceutical drug that will prevent or reduce the risk of occurrence of the biological or medical event that is sought to be prevented in a tissue, a system, animal or human by a researcher, veterinarian, medical doctor or other clinician.

(see page 11, line 29 – page 12, line 3 of the present specification). As defined by the present specification, "treating" and "amount effective for treating" are inclusive of "**preventing**" and, thus, the claims are read to be inclusive of the use of the claimed compounds to prevent a number of different diseases/conditions having vastly different etiologies which is clearly beyond the scope of the instant invention. The term "**prevent**" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "**treat**" especially since it is well accepted in the medical art that the vast majority of afflictions/disorders suffered by

mankind cannot be totally prevented with current therapies. Applicant has not demonstrated the prevention of any of the diseases in-vitro or even in a mouse/rat in order to provide some reasonable nexus between the compounds instantly claimed and the prevention of a disease. Therefore, in order to practice the claimed invention commensurate in scope with the claimed invention, the skilled artisan would have to determine the ability of the claimed compounds to prevent each condition which would require a determination of a person prone to said diseases and, thus, in need of preventive therapy.

6. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not

perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to (a) treating glucocorticoid receptor mediated disease (claim 12); (b) treating a vast array of specific conditions (claims 13 and 14) and (c) modulating the activation, repression, agonism and antagonism of glucocorticoid receptor (claims 15 and 16), i.e., glucocorticoid receptor mediated condition by administering the claimed compound(s). The present specification provides support by providing an assay for determining the binding affinity of the claimed compounds (see page 32, lines 10-26).

The state of the pharmaceutical art is such that screening in vitro and in vivo is utilized to determine the desired effect of pharmaceuticals. There is no absolute predictability of pharmaceuticals and, thus, one of ordinary skill in the art would not accept any therapeutic regimen on its face.

Because the pharmaceutical art is unpredictable, it requires each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F 2d. 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is needed in order to satisfy the statute.

Here, the instantly claimed invention is highly unpredictable because of the complexity of the human body and the differences in the underlining cause(s) of the vast array of conditions encompassed by the instant invention (see for example, claims 13-14). In addition, there is a lack of showing in the medical art of the utilization of a single agent in the treatment of all of the disorders encompassed by the claimed invention.

For example, the art lacks a showing of treatment of "cancer" in general utilizing a single agent. Therefore, the skilled artisan would doubt the claimed compounds would be effective in treating cancer in general and he would especially doubt said compounds would be effective in treating all the conditions encompassed by the instant claims.

Therefore, in the absence of a showing of correlation between all conditions encompassed by the instant claims and the effectiveness of the claimed compounds in treating said conditions, one of skill in the art would be unable to fully predict the effect of administration of the claimed compounds in the treatment of every condition as encompassed by the instant claims.

As stated above, the only guidance given in the present specification is an assay useful in determining the binding affinity of the claimed compounds, which is minimal. Thus, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have to engage in undue experimentation to determine the condition(s) treatable by the claimed compounds, with no assurance of success.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628